PEARL COHEN ZEDEK LATZER

5 Shenkar Street
P.O. Box 12704
Herzlia 46733, Israel
Tel +972.9.972.8000
Fax +972.9.972.8001

10 Rockefeller Plaza
Suite 1001
New York, NY 10020
USA
Tel 212.632.3480
Fax 212.632.3489

www.pczlaw.com

FACSIMILE

Direct Dial: 972-9-972-8006
Direct E-mail: JoelS@pczlaw.com

Date: May 25, 2005
To: Examiner Robert L. Nasser
Company: USPTO
From: Joel Stein, Adv.
Our Ref.: P-3571-US
Subject: 09/963,950 interview today at 3PM
Fax No.: +1-703-872-9306
# of Pages: 28 (including this one)

Message:

Dear Examiner Nasser:

Please find attached the Provisional Patent Application No. 60/180,960 filed on February 8, 2000 by Mullick et al as was cited for priority to 09/759,398 and Provisional Patent Application No. 60/235,583 filed on September 27, 2000 by Meron, Gavriel as was cited from priority to 09/963,950. We would like to address these applications in our telephone interview today at 3PM.

Yours sincerely,

Joel Stein, Adv.
Pearl Cohen Zedek Latzer

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60/180960

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PTO/SB/16 (2-98)
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Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

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PROVISIONAL APPLICATION FOR PATENT COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION FOR PATENT under 37 CFR 1.53 (c).

INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Tarun Rangopal Sudhir K. Padmanbhan P.	Mullick Nair Datta Nair	Beachwood, OH Ellicott City, MD Baltimore, MD Ellicott City, MD

[ ] Additional inventors are being named on the ___ separately numbered sheets attached hereto

TITLE OF THE INVENTION (280 characters max)

Miniature Ingestible Imaging Capsule

CORRESPONDENCE ADDRESS

Direct all correspondence to:

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OR

[X] Firm or Individual Name	Tarun Mullick				
Address	26200 George Zeiger Dr. Suite 411				
Address					
City	Beachwood	State	OH	ZIP	44122
Country	USA	Telephone		Fax	

ENCLOSED APPLICATION PARTS (check all that apply)

[X]	Specification Number of Pages	12	[X]	Small Entity Statement	
[X]	Drawing(s) Number of Sheets	3	[X]	Other (specify)	Small Entity Statement Additional Page

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

[X] No.

[ ] Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE Tarun Mullick

TYPED or PRINTED NAME Tarun Mullick

TELEPHONE 216-360-9548

Date 1/20/04

REGISTRATION NO. (if appropriate)

Docket Number:

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STATEMENT CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) & 1.27(b))—INDEPENDENT INVENTOR

Docket Number (Optional)

Applicant, Patentee, or Identifier: Tarun Mullick, Rangopal Nair, Sudhir K. Dutta, Padmanabhan P. Nair

Application or Patent No.: N/A

Filed or Issued: Filed

Title: Miniature Ingestible Imaging Capsule

As a below named inventor, I hereby state that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees to the Patent and Trademark Office described in:

- [x] the specification filed herewith with title as listed above.
- [ ] the application identified above.
- [ ] the patent identified above.

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Tarun Mullick	Rangopal Nair	Sudhir K. Dutta
NAME OF INVENTOR	NAME OF INVENTOR	NAME OF INVENTOR
Signature of Inventor	Signature of Inventor	Signature of Inventor
1/21/00	1/13/00	1-14-00
Date	Date	Date

ADDITIONAL INVENTOR'S SIGNATURE IS LOCATED ON THE 1 SEPARATELY NUMBERED SHEET ATTACHED.

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INVENTOR(S)		
Given Name (first and middle [if any])	Family Name or Surname	Residence (City and either State or Foreign Country)
Gavriel	MERON	Petach Tikva, Israel

☐ *Additional inventors are being named on the separately numbered sheets attached hereto*

TITLE OF THE INVENTION (280 characters max)

A SYSTEM AND METHOD FOR POST SURGERY MONITORING

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☒	Firm or Individual Name	Eitan, Pearl, Latzer & Cohen-Zedek			
Address	One Crystal Park, Suite 210, 2011 Crystal Drive				
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ENCLOSED APPLICATION PARTS *(check all that apply)*

☒ Specification *Number of Pages* [ ] ☐ Small Entity Statement

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The invention was made by an agency of the United States Government or under a contract with an agency of the United States Government.

☒ No.

☐ Yes, the name of the U.S. Government agency and the Government contract number are: _____

Respectfully submitted,

SIGNATURE _____

TYPED or PRINTED NAME: Mark S. Cohen

TELEPHONE: (703) 486-0600

Date: 27 / Sep / 2000

REGISTRATION NO. *(if appropriate)*: 42,425

Docket Number: P-3571-USP

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Provisional Patent Application

Of

Tarun Mullick, Ramgopal Nair, Sudhir K. Dutta, and Padmanabhan P. Nair

for

TITLE: MINIATURE INGESTIBLE IMAGING CAPSULE

Field of the Invention

This invention relates to methods of imaging the gastrointestinal tract for medical diagnosis. More specifically this invention relates to noninvasive, noninterventional methods for internal examination of the gastrointestinal tract that are novel, significantly more convenient, comfortable, lower in cost and more advanced compared with current invasive methods such as colonoscopy, sigmoidoscopy, esophagogastroduodenoscopy and push enteroscopy.

Background of the Invention

The mammalian gastrointestinal tract comprises the esophagus, stomach, small intestine, and colon. Physicians image the interior of the gastrointestinal tract to aid in the diagnosis and treatment of many illnesses such as ulcers, growths, cancers and bleeding spots. More specifically these conditions include colorectal cancer, colonic polyposis, inflammatory bowel disease, irritable bowel syndrome, Barrett's esophagus, peptic ulcer disease, and dyspepsia.

Heart burn and indigestion afflicts over 15 million Americans, frequently mimicking heart attack. Colorectal cancer, for example, is the 2nd leading cause of cancer death in the United States, with 133,500 new cases detected in 1996, 54,900 (41%) of

which resulted in death [1]. Survival rates improve and treatment costs decline with early detection of the process [2,3]. However, regular screening for colorectal cancer is not performed for the vast majority of the populace due to the high cost of such programs and more importantly the reluctance of a healthy population at risk to undergo an invasive procedure again and again for surveillance against cancer. As a result over two-thirds of patients are diagnosed with advanced disease [4]. The only low-cost noninvasive screening tests for colorectal cancer are fecal occult blood tests, which look for the presence of fecal occult blood in stool specimens. These tests exhibit poor sensitivity due to the fact that malignant growths of the colon have to be fairly large before they start to bleed. Furthermore, there are many other reasons for bleeding into the GI tract (e.g. Ulcers) which lead to low specificity of the test and a high probability of false positives [5,6]. Even with the poor characteristics of fecal occult blood tests, the American Cancer Society estimated that the regular use of the test in men over age 50 could produce a 15% reduction in mortality [1].

More sophisticated approaches such as colonoscopy and related gastrointestinal imaging methods, namely, sigmoidoscopy and esophagogastroduodenoscopy, are more ef-

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1 Agency for Health Care Policy & Research (AHCPR) *Research Activities* 200:15-16, 1997.

2 Brown, M.L. and Fintov, L. The economic burden of cancer. In Greenwald, P. Kramer, B.S., and Weed, D.L., eds *Cancer Prevention and Control*. New York, Marcel Decker, pp 69-81, 1995.

3 Healthy People 2000: Nutritional Health Promotion and Disease Prevention Objectives. U.S. Department of Health and Human Services, Public Health Service, DHHS Publication no. (PHS) 91-50212, p.423, 1991.

4 Eddy, D.M. Screening of colorectal cancer *Ann. Int. Med.* 113:373, 1990

5 Eisner, M.S., and Lewis, J.A. Diagnostic yield of positive FOBT found on digital rectal examination. *Arch. Int. Med.* 151:3180, 1991.

6 Rockey, D.C., Koch, J., Cello, J. P., Sanders, L.L., McQuaid, K. Relative Frequency of Upper Gastrointestinal and Colonic Lesions in Patients with Positive Fecal Occult-Blood Tests.

fective because they can identify abnormalities before the occurrence of late-stage symptoms (e.g., blood in the stools for colonic tumors or tarry stools for peptic ulcers). However, for the following reasons, these methods see limited use:

1. They are invasive and uncomfortable to the patient, requiring sedation so that a flexible fiberoptic tube can be inserted into the tract. This is a major limitation of these tests in their application to healthy asymptomatic individuals for repeated examinations (every 1 – 3years).
2. In addition these tests are expensive with an average cost of colonoscopy of $1250/case, requiring the presence of a physician and other personnel.
3. They are inconvenient, requiring the patient to take a purgative, fast overnight, and remain incapacitated during the procedure.

Thus there is a medical and economic benefit for an inexpensive noninvasive, miniature, ingestible imaging device that allows the patient to use the device while still performing normal activities of daily living. Furthermore it would eliminate the need of highly trained personnel for its operation. The market for such a device is huge. In light of the high cost of current imaging methods (and their subsequent limited and late-stage application), hospitals, clinical laboratories, HMO's, will be eager to employ these devices as a cost-containment strategy.

Description of Prior Art

Colonoscopy

The most common diagnostic procedure for colonic examination is colonoscopy. This procedure involves the optical examination of the entire colon using a device known as a colonoscope. A colonoscope comprises a flexible tube containing a fiber optic imaging and illuminating device and a device to resect portions of the surface of the in-

testinal tract. The colonoscope is inserted into the rectum and can be maneuvered to the ileo-cecal junction (the start of the colon). The operator views the image on a video display. The medical team performing this procedure usually comprises a gastroenterologist, specially trained nurses and at times and anesthesiologist. Polyps (tumors) are identified visually and biopsied. If examination of the specimen reveals malignancy, a surgical team resects the regions containing the tumors Usually, this is followed by a period of chemotherapy, administered to fight unobserved or secondary tumors; annual colonoscopies may be prescribed. Considering the cost of the colonoscopy alone ($800 minimum), a yearly colonoscopy for all patients over age 48 for instance, would be prohibitively expensive. Colonoscopy for asymptomatic patients is seldom prescribed.

Sigmoidoscopy

The sigmoidoscope is a similar to a colonoscope, but can only be used to image only the lower 2/3 of the colon. Although simpler than a colonoscope, its operation still requires the presence of a highly trained physician and often requires sedation.

Esophagogastroduodenoscopy

The esophagogastroduodenoscope is used to image the upper gastrointestinal tract-namely the esophagus, the stomach and the duodenum. It is inserted through the mouth. Again, its operation requires the presence of a highly trained physician and often requires sedation.

Push Enteroscopy

The push enteroscope is used to image the third and fourth portions of the duodenum and the proximal jejunum. It is inserted through the mouth. Its operation requires the presence of a highly trained physician and requires sedation.

Non-tethered Devices

The present invention is a type of non-tethered device that is ingested by the patient,

thereby passing through the entire gastrointestinal tract, sending images and data through a telemetry means. There are several prior systems that use an ingestible device to provide data on the internal state of a patient. The Heidelberg capsule relays pH information through a radio frequency (RF) link, and can release medicament on a signal from an external transmitter. The Konigsberg capsule monitors temperature and uses a RF link. The Cortemp pill, which is commercially available at this time, also monitors the body temperature, but uses a near-field magnetic link.

Relevant U.S. Patents:

4844076 - temperature monitoring pill

5279607 - triggered medicament release + tracking

5415181 - multichannel implantable modulation circuit

5279607 - telemetry capsule and process

5481262 - implantable transponder - temperature

5827190 - endoscope having an integrated CCD sensor

5842977 - multichannel pill with integrated optical interface

Summary of the Invention

This invention is a miniature non-digestible capsule, ingestible by a human or other animal, comprising an impermeable membrane, a transparent window, an imaging device, a pose detector, a telemetry device, and a power supply, and an external unit comprising a data reception device, a recording device, and a pose reference frame. Ingested by a patient, the capsule will pass through the entire gastrointestinal tract of the patient, providing real-time circumferential images of the esophagus, stomach, small intestine, and colon, which can be viewed and recorded by the physician. The capsule exits the patient through the rectum. The device can either be discarded or reused by replacing the membrane.

A miniature color imaging device, such as a CCD array and lens, and an illumination

device, such as an RGB diode array or similar low-power white light source provide real-time color images of the gastrointestinal tract. The image is transmitted in real-time by a telemetry device, such as a miniaturized UHF video transmitter, to an external reception device, such as a television monitor and a recording means, such as a video cassette recorder. The capsule may be weighted in such a way as to maintain a particular orientation in the stomach. In simultaneous operation with the imaging system is a 6 degree-of-freedom pose detection device that calculates the real-time pose of the capsule, thus tracking the device through patient's body relative to a fixed external reference frame, that may be strapped to the patient's abdomen. In one arrangement, this device is a passive beacon which is tracked by an external detector strapped to the patient's body, which relays pose data that is correlated with received video data by a computer. Alternatively the pose detector may be an active device whose data is either multiplexed with the image data prior to transmission or is sent on a second channel of the telemetry device. An electric power source such as a lithium battery provides sufficient energy to power all the component devices for a time period of at least 72 hours, the maximum transit time for the gastrointestinal tract. (The average transit time is 48 hours, with a range of 24 to 72 hours.)

Note that the pose detector is not absolutely necessary for the successful use of this device: a trained physician will likely be able to infer the approximate location of a given image from its appearance and the time it is recorded (since the range of transit times through the parts of the tract are well documented).

In another form, the capsule includes a reception capability, such as a radio-frequency receiver, and an internal microprocessor that allows instructions to be relayed from the physician to the capsule. Miniature motors allow the imaging system to be reoriented, or provide some form of controlled mobility. An expandable bladder attached to capsule can be expanded to stabilize the capsule or slow its motion through the tract. The system may also include on-board signal processing circuitry to automatically stabilize the image. Alternatively a micro-machined mechanical stabilization platform can be

built into the imaging system. The imaging system may also include a means such as a prism or fiber-optic device, to direct multiple images onto the imaging device.

We have built a 1:8 scale prototype capsule using off-the-shelf components. The system incorporates a 1/3" CCD video camera, a light source, an UHF video transmitter with antenna, and a lithium battery power supply. Even smaller CCD cameras are currently available off-the-shelf, such as the 1/6" array Texas Instruments TC211 192 pixel by 165 pixel sensor, which costs about $25/unit for 100-999 units for the imager alone.

Brief Description of the Drawings

Figure 1 is a diagram showing the main components and signal flow for the system.

Figure 2 is an exploded view of the capsule.

Figure 3 is a perspective and sectional view of the capsule with an external lens.

Figure 4 is a perspective view of the capsule with an internal lens and a transparent window in the membrane.

Figure 5 is a perspective and capsule with an internal lens and a flat transparent window in the membrane.

Figure 6 is a diagram of the external components of the system.

Detailed Description of the Drawings

Referring to **Figure 1**, an illuminator inside the capsule projects light into the gastrointestinal tract. Images enter the capsule through an imaging system, impinging on an imaging array, the signal from which is then transmitted to a receiver outside of the

capsule. A power source inside the capsule provides power to the imaging array, transmitter, and illuminator. The data from the receiver is then relayed to a recording and display device. Simultaneously, a pose detection system tracks a beacon located inside the capsule and relays tracking information to the recording/display system.

Referring to Figure 2, the capsule comprises an anterior membrane 1 through which images are viewed, a lens 2, and illumination device 3 (comprising a light source and projection means), an imaging array 4, transmitter 5, a pose beacon 6, a power source 7, and a posterior membrane/antenna 8.

Capsule

The anterior capsule 1 is made of a non-allergenic, nondigestible, impervious material with at least one transparent window or opening for the lens 2. The posterior capsule 8 is also made of a non-allergenic nondigestible impervious material, and may include an integrated antenna for the transmitter.

Lens/Imaging System

The lens 2 may be mounted behind a transparent window in the capsule, or it may be mounted in an opening in the capsule so that its front surface is exposed to the outside.

Regarding the design of the lens 2, they're a several options. Possible candidates are a plastic or glass lens, a prism or a fiber optic bundle. One advantage of a fiber optic bundle is that its front end can be designed to image several views of the external environment, thus producing a composite image on the array plane. The focal length of the imaging system must be small enough to achieve infinite focus at approximately 1 mm. One advantage of an internal lens is that the lens can be mounted at an optimal distance to maintain focus.

Figure 3 shows a capsule with an external lens 9. The front surface of the lens is ex-

posed to the external environment. In case the desired lens material is not ideal for limiting fluid adherence, such that fluids may build up on its surface and reduce image quality, it may be that a transparent window is a preferred method. Figure 4 shows a capsule with an internal lens and a transparent window 10 in the anterior end of the capsule. The transparent window should be made of a material to which mucous and other biological materials will not adhere. An additional advantage of an internal lens design is that the lens can be mounted at an optimal distance to maintain focus. Figure 5 shows a capsule with an internal lens and a flat transparent window 11 in the membrane.

Camera

Referring back to Figure 2, for the camera 4 the simplest and most cost effective imaging system is the CCD (charge-coupled device) array. Color ¼" CCD arrays can be purchased for under $100US. It may be necessary to provide shielding for the CCD array to prevent RF interference from the transmitter. A slightly oversized CCD array plus digital signal processor (DSP) circuitry can be included to allow real-time stabilization of the image, by time-correlating a series of images from the oversized array to eliminate image blur and shake electronically. New micromachining technologies may be included in the array itself to provide image stabilization. These devices would essentially incorporate a passive or active damping system into the CCD chip itself. To maximize space for additional circuitry such as a DSP for on-board image processing, signal multiplexing and signal encoding can be constructed on flexible circuit board that can wrap circumferentially around the inside of the capsule.

Light Source

The specification of the light source 3 depends to a certain extent on the choice of imaging array. The use of a low-lux imaging array obviates the need for a high-power light source. The source should approximate a white light source so that a color image can be obtained. Methods for producing a white light source at very low power in-

clude 3-diode light source, inorganic LEDs, and full-color organic electroluminescent sources. Figure 2 shows a toroidally shaped source backed by a ring-semi-parabolic mirror, both concentric with the imaging window/lens.

Pose Detector

The pose detector/beacon 5 provides a useful auxiliary piece of information, the real-time position of the capsule relative to the patient's body. This information will eliminate the discomfort of a tether or the guesswork necessary in pinpointing the location of abnormality by simple visual examination of the video or by time-tracking the video. There currently exist several proven methods to determine the 6 degree-of-freedom pose of a remote object, most often used in robotics to track mobile robots or to digitize human movements, for example in hand-tracking and head-tracking controllers. These devices use a RF or EM beacon that reflects signals from an externally fixed transmitter, somewhat like a miniature radar system. Distances are typically limited to a few meters cubic, which fall well within the specifications for this device. The beacons themselves are generally passive devices, hence will not draw power from the on-board battery. External stations that can be strapped or belted to the patient provide the signal sources. Given the recorded time-space tracking information, there are numerous ways to develop a correspondence between the video images and the patient's internal structures. For example, a computer can overlay the time-parametrized space-path of the pill on an image based on a CAT scan or MRI of the patient, or over a computer-generated model based on the patient's body size and shape. The video can then be synchronized with the pill's motion on the computer screen.

Transceiver

In its simplest embodiment, this device requires only a transmitter 5 rather than a transceiver. The simplest approach is to use a miniature amplitude modulation (AM) video transmitter in the 400MHz-1.5Ghz region. Other standard transmission methods include frequency modulation (FM), pulse-code modulation (PCM), and frequency

shift keying (FSK). For more complex arrangements, an on-board receiver will allow the base station to communicate with the pill.

Power Source

The power source 7, is a device of relatively high energy density, capable of 10's of mA in the 0.5-9V range (these numbers are for the current commercially available CCD and RF devices). The power source must fit within approximately ½ the volume of the pill, approximately 1/3 cc, and must run the device for 72 hours at the body temperature (approximately 37 °C). The primary draw will probably be the light source followed by the transmitter and the imaging system. Additionally, the nature of the imager will determine the amount of light necessary to provide the desired image quality; consider for example, that current off-the-shelf CCD arrays operate down to 0.1 lux.

Off the shelf 1/3" CCD board-cameras have power requirements in the range of 50-200 mA at 9VDC. However a portion of this requirement is for the line driver, which enables the output signal to be sent on a long coaxial cable (eg, 60'+). Since a line driver is not a requirement for this device, we can expect a much lower current requirement. Off-the-shelf video transmitters require approximately 50 mA current at 9V. These devices however, transmit signals at a design distance of 100-500'. Hence our requirements will require a much lower power device.

The battery may also be designed to act as the ballast to orient the pill in the stomach. In other words, the battery will be situated to the posterior of the capsule.

The following table lists lithium battery types currently used in implantable biomedical applications:

Battery Type	Current Application
Lithium Iodine	These are currently used in implantable cardiac pacemakers: microamp range over long periods, a 4mm thick 10mm radius disc has an energy volume of 400 mA-hrs.
Lithium Silver Vanadium Oxide	Used in both high amperage applications (e.g., defibrillator) and medium amperage applications (e.g., neurostimulators). Current of 50 mA continuous.
Lithium Carbon Monofluoride	Used in medium amperage applications such as neurostimulators and drug infusion pumps

The battery will include some form of integrated on-off switch for the pill, activated for example by twisting the posterior capsule with respect to the anterior capsule, or similar method that will not be accidentally actuated by the peristalsis of the gut.

External Components

Referring back to **Figure 1**, there are several external components to the external station **12**. The basic system only requires a video receiver **13** to capture the image information. More complex design will include a transmitter in the external station and a receiver in the pill, enabling the external controller to transmit instructions to the pill itself. The pose base station **14** is a powered device that produces an RF signal or EM field that allows the pill's beacon to be tracked. The device can be strapped to the patient's body. The pose data can be read by the computer **15** and correlated with the image data. The computer **15** may be used to record and integrate the image and pose data and data from other sources such as a CAT scan or MRI, and produce a useful display **16** for the physician.

A SYSTEM AND METHOD FOR POST SURGERY MONITORING

FIELD OF THE INVENTION

The present invention relates to post surgery monitoring. More specifically, the present invention relates to a system and method for post surgery monitoring which utilize an imaging device at the surgery site during the critical post surgery hours.

BACKGROUND OF THE INVENTION

In the time immediately after surgery patients frequently experience organ functional problems.

For example, during surgery in the gastrointestinal tract the blood pressure at the vicinity of the surgical site is reduced and peristalsis is arrested. After surgery the blood pressure increases and peristalsis is resumed sometimes causing bleeding from the surgical site into the intestine lumen.

Also, for example, in treating coronary artery disease, it is sometimes necessary to bypass coronary arteries with a vascular graft which is surgically attached to the heart to circumvent a blocked coronary artery. After surgery cardiac functional problems may occur due to build-up of stenotic lesions or other obstructions to the flow of blood through the implanted graft.

Postoperative monitoring of the gastrointestinal tract is important to avoid letting too much time elapse before blood loss into the intestine is detected.

Similarly, it is important that the condition of a vascular graft be monitored, post-surgery, to detect the further build-up of stenotic lesions or other obstructions to the flow of blood through the implanted graft.

Various catheterization procedures are known for assessing the flow characteristics of a blood vessel or blood vessel graft. However, the introduction of catheters into the vascular system may result in damage to blood vessels.

US 4,915,113 to Holman describes an implantable system for monitoring blood flow through surgically implanted grafts. The system, which comprises Doppler crystal transducers, utilizes a subcutaneously implanted electrical plug-type connector, accessible through an incision at the implant site, and electrical conductors to connect terminals on that plug to the Doppler crystal transducers.

Ultrasound echo imaging is known for visualization and examination of a patient's heart. However, methods of echocardiography do not always result in good quality images after cardiac surgery.

SUMMARY OF THE INVENTION

The present invention provides a system and method for post surgery monitoring of surgical operations which provide camera or video images of the surgery site during the critical post surgery hours. The system and method of the invention enable an external operator to directly observe changes occurring at the surgery site, such that pathological post surgery occurrences, such as bleeding, can be detected at their onset and immediately treated.

The system and method of the invention further provide post surgical monitoring of the gastrointestinal tract utilizing any appropriate sensing device (pH meter, blood detector, imaging device etc.) with out having to leave an opening in the patient or cut the patient twice for retrieval of the monitoring system.

The system of the invention comprises a housing having an optical window, said housing configured for being transiently immobilized in the vicinity of a surgical site; at least one imaging device, such as a CCD or CMOS chip contained within the housing; a transmitter which transmits the output of the imaging device; and a reception system for receiving the transmitted output.

Another system according to the invention comprises a housing configured for being transiently immobilized in the vicinity of a surgical site in the gastrointestinal tract; at least one sensing device contained within the housing; a transmitter which transmits the output of the sensing device; and a reception system for receiving the transmitted output.

The method of the invention comprises the steps of transiently immobilizing an imaging device in the vicinity of a surgical site;

imaging the surgical site; and receiving images of the surgical site externally to the surgical site.

Another method according to the invention for post surgical monitoring of a surgical site in the gastrointestinal tract comprises the steps of transiently immobilizing a sensing device in the vicinity of the surgical site; transmitting out put from the sensing device; and receiving the transmitted out put externally to the surgical site.

BRIEF DESCRIPTION OF THE FIGURES

The present invention will be understood and appreciated more fully from the following detailed description taken in conjunction with the figures in which:

Figure 1 is a schematic illustration of the system in accordance with an embodiment of the invention; and

Figure 2 is a tangential section illustration of the system in accordance with another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to a system and method for post surgery monitoring which provide information related to the surgical site during the critical post surgery hours.

For post surgical monitoring of a surgical site along the gastrointestinal tract there is provided a system which includes a sensing device, a transmitter which transmits the output of the sensing device, a reception system for receiving the transmitted output and a power source which provides power to the elements of the system. At least the sensing device is contained in a housing which is configured for being transiently immobilized in the vicinity of a surgical site (further described in the Figures) .

The sensing device may be any device that is adapted for being placed in the vicinity of a surgical site along the gastrointestinal tract, that can sense environment conditions such as the presence of blood, pH, temperature,

electrical impedance of tissues etc., and that can transmit (such as by radio) output relating to changes in the environment conditions.

For post surgical monitoring of surgical sites not only along the gastrointestinal tract there is provided a system in which the sensing device is an imaging system. The imaging system typically includes at least one illumination source such as a white LED (light emitting diode) and an imaging device such as a CCD or CMOS chip. The imaging system may further include an optical system for imaging an area of interest onto the imaging system. The optical system may comprise mirrors and/or lenses for collimating the light from the illumination source.

In accordance with this embodiment the reception system receives the transmitted video output and may include a) an antenna array capable of surrounding a body for receiving the transmitted video output and for producing a plurality of received signals and b) a demodulator capable of transforming the plurality of received video signals into a single video datastream.

For example, a system which includes a camera system, a transmitter and a receiving system such as described in US 5,604,531, may be used in the present invention. US 5,604,531, which is assigned to the common assignee of the present invention, is hereby incorporated by reference.

The imaging system provides direct visual information of the surgical site such that visibly detectable changes at the surgical site, such as bleeding, swelling etc. can be seen by an external operator. The imaging system may further comprise a detector coupled to the imaging device which is optically changed in response to environment conditions. The optical change in the detector is imaged and transmitted to alert an external operator of the changed

conditions. For example, the imaging system may comprise a pH meter which undergoes a color change in response to pH changes in its vicinity. Also, the imaging system may comprise a detector of chemical substances, such as blood components, which undergoes a change in color in response to the presence of the chemical substances. In both cases a change in color will be detected by the imaging device and its image will be transmitted.

The sensing device, such as an imaging system, may further be in communication with a processor for analyzing the data detected by it. For example, images of the surgical site may be transmitted to a processor where they are analyzed for the presence of blood (by detecting certain changes in color or by detecting red) and for the concentration of blood. The image may then be received by the external operator including additional information, generated by the processor, regarding the bleeding at the surgical site. Further, the system may include means for alerting the external operator. The means for alerting the external operator are in communication with the processor. Thus, when the presence of blood is detected by the processor a signal, such as a flashing light or an alarm, may be activated to alert the external operator.

The housing is configured for being transiently immobilized in the vicinity of a surgical site. Also, it is necessary for a housing which includes an imaging system to have an optical window through which the surgical site can be imaged.

Thus, for post surgical monitoring according to the invention, an imaging device is transiently immobilized in the vicinity of the surgical site and the site is imaged. Typically, imaging of the site is aided by illumination. The

images are then transmitted and received externally to the surgical site at a work station where an external operator can monitor the surgical site.

Two embodiments of the invention are illustrated in Figures 1 and 2. The housing illustrated in Figure 1 is a capsule 10 designed to passively transverse the gastrointestinal tract. Capsule 10 comprises an optical window 14 behind which are positioned illumination sources 12 and an imaging device 16. The other part of the capsule 17 houses other elements of the system, such as a processor, the transmitter and power source. Capsule 10 has two rings 13 on its perimeter, about equally distanced from each other. The rings 13 are fit into depressions in the capsule 10 perimeter so that they do not protrude from capsule 10 perimeter and do not obstruct the capsule 10 passage through the gastrointestinal tract. Ring 13 are used for sewing the capsule 10 to a desired location in the vicinity of a surgical site.

Figure 2 schematically illustrates a tangential section of capsule 20 which similarly to capsule 10 comprises an optical window 24 behind which are positioned illumination sources 22 and an imaging device 26. Other elements of the system, such as a processor, the transmitter and power source are housed in the other part of the capsule 27. Capsule 20 is ellipsoid shaped having an indentation 23 circling the entire capsule perimeter more or less around the capsule center. Indentation 23 forms a groove suitable for accommodating the operating doctor's thread 25. The capsule 20 is thus fastened to the surgical site by thread 25 which surrounds the capsule 20 and which is anchored into the patient's body.

Typically, the thread used for suturing the capsule 10 or 20 to a surgical site in the gastrointestinal tract is thread which will disintegrate with time. Thus, a doctor performing an operation in the gastrointestinal tract can activate the system (initiate imaging) in capsule 10 or 20 and sew in the capsule 10 or 20 at the operation site in the gastrointestinal tract prior to closing the surgical incision. The imaging, which may be continuos or periodical, can last up to 24 hours which is the critical post surgical period. During this time the surgical site will be imaged and the images will be transmitted to the receiving system, such as an external workstation where the images will be monitored by an external operator. At some point in time, either during the imaging process or after its termination, the sutures sewn through rings 13, or around capsule 20 in indentation 23, which have been immobilizing the capsule to the surgical site, will disintegrate and capsule 10 or 20 will be released into the gastrointestinal tract. The capsule 10 or 20 will be free to travel through the tract driven by peristalsis and will be naturally excreted from the body.

The system and method of the invention thus enable post surgical monitoring in the gastrointestinal tract with out having to leave an opening in the patient's body or having to cut the patient a second time in order to retrieve the monitoring system.

In other embodiments a housing comprising an imaging system may be designed for other surgical sites than the gastrointestinal tract, such as the lungs or blood vessels. In these embodiments a housing which comprises an optical window may comprise a clip for attaching onto a site of interest at the time of surgery and for being removed, for example, through an incision or through a transthoracic or transesophageal opening.

It will be appreciated by persons skilled in the art that the present invention is not limited by what has been particularly shown and described herein above. Rather the scope of the invention is defined by the claims which follow:

CLAIMS

1. A system for post surgery monitoring comprising

a housing having an optical window, said housing configured for being transiently immobilized in the vicinity of a surgical site;

at least one imaging device contained within the housing;

a transmitter which transmits the output of the imaging device; and

a reception system for receiving the transmitted output.

2. A system according to claim 1 wherein the housing is configured for being sewn to the vicinity of a surgical site.

3. A system according to claim 1 wherein the imaging device is a CCD or CMOS chip.

4. A system for post surgery monitoring in the gastrointestinal tract comprising

a housing configured for being transiently immobilized in the vicinity of a surgical site in the gastrointestinal tract;

at least one sensing device contained within the housing;

a transmitter which transmits the output of the sensing device; and

a reception system for receiving the transmitted output.

5. A method for post surgical monitoring comprising the steps of

transiently immobilizing an imaging device in the vicinity of a surgical site;

imaging the surgical site; and

receiving images of the surgical site externally to the surgical site.

6. A method for post surgical monitoring of a surgical site in the gastrointestinal tract comprising the steps of

transiently immobilizing a sensing device in the vicinity of the surgical site;

transmitting out put from the sensing device;

receiving the transmitted out put externally to the surgical

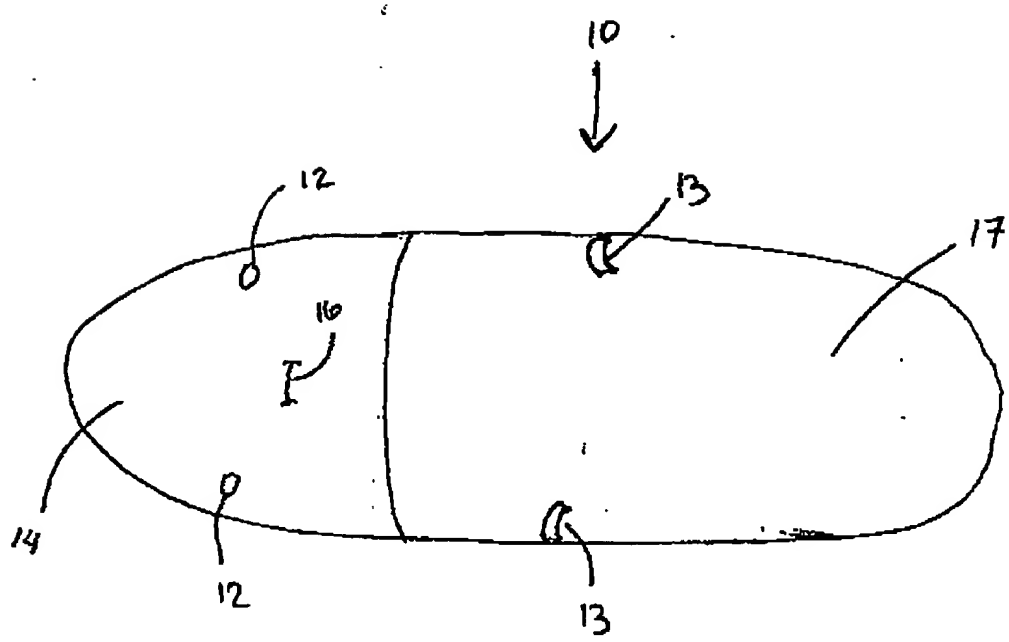

FIGURE 1

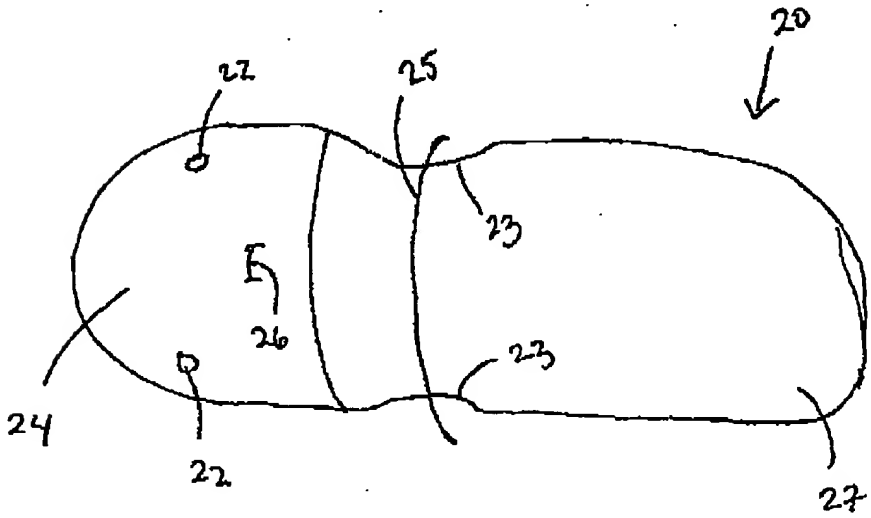

FIGURE 2